3 Summary of Safety and Effectiveness

MAR 13 2007

Date Summary Prepared: February 15, 2007

Applicants Name: Ricerfarma Srl
Via Egadi, 7-20144
Milano, Italy

Contact Person: Paul Ketteridge, (Consultant to Ricerfarma)
303 Patleigh Road
Catonsville, MD 21228
443 729-0836
p.kett@comcast.net

Device Name: Gengigel® Prof Gel.
Classification Name: Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code: MGQ
CFR Section: None
Device Class: Unclassified
Classification Panel: General and Plastic Surgery

Indications: Gengigel® Prof Gel adheres to the oral mucosa and forms a protective film over the lesions and irritation due to various etiologies, including: oral surgery; traumatic ulcers caused by, braces or ill fitting dentures; diffuse aphthous ulcers; and oral mucositis/stomatitis (which may be caused by chemotherapy or radiotherapy). Gengigel® Prof Gel relieves pain by providing a barrier to protect the area from ongoing insult and discomfort.

Predicate Device

K013056
Gelclair® Oral Gel
Sinclair Pharmaceuticals, Ltd
Godalming, Surrey,UK
Product Code-MGQ

K053342

3 Summary of Safety and Effectiveness

Date Summary Prepared: February 15, 2007

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Via Egadi, 7-20144
Milano, Italy

Contact Person: Paul Ketteridge, (Consultant to Ricerfarma)
303 Patleigh Road
Catonsville, MD 21228
443 729-0836
p.kett@comcast.net

Device Name: Gengigel® Prof Fluid.
Classification Name: Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code: MGQ
CFR Section: None
Device Class: Unclassified
Classification Panel: General and Plastic Surgery

Indications: Gengigel® Prof Fluid adheres to the oral mucosa and forms a protective film over the lesions and irritation due to various etiologies, including: oral surgery; traumatic ulcers caused by, braces or ill fitting dentures; diffuse aphthous ulcers; and oral mucositis/stomatitis (which may be caused by chemotherapy or radiotherapy). Gengigel® Prof Fluid relieves pain by providing a barrier to protect the area from ongoing insult and discomfort.

Predicate Devices

K013056
Gelclair® Oral Gel
Sinclair Pharmaceuticals, Ltd
Godalming, Surrey,UK
Product Code-MGQ

K053342

3 Summary of Safety and Effectiveness

Date Summary Prepared: February 15, 2007

Applicants Name: Ricerfarma Srl
Via Egadi, 7-20144
Milano, Italy

Contact Person: Paul Ketteridge, (Consultant to Ricerfarma)
303 Patleigh Road
Catonsville, MD 21228
443 729-0836
p.kett@comcast.net

Device Name: Gengigel® Junior.
Classification Name: Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code: MGQ
CFR Section: None
Device Class: Unclassified
Classification Panel: General and Plastic Surgery

Indications: Gengigel® Junior provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: oral surgery; traumatic ulcers caused by braces or ill fitting dentures; and aphthous ulcers.

Predicate Device

K040950
Aloclair™ Oral Gel
Sinclair Pharmaceuticals, Ltd
Godalming, Surrey,UK
Product Code-MGQ

K053342

3 Summary of Safety and Effectiveness

Date Summary Prepared: February 15, 2007

Applicants Name: Ricerfarma Srl
Via Egadi, 7-20144
Milano, Italy

Contact Person: Paul Ketteridge, (Consultant to Ricerfarma)
303 Patleigh Road
Catonsville, MD 21228
443 729-0836
p.kett@comcast.net

Device Name: Gengigel® Spray.
Classification Name: Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code: MGQ
CFR Section: None
Device Class: Unclassified
Classification Panel: General and Plastic Surgery

Indications: Gengigel® Spray provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: oral surgery; traumatic ulcers caused by braces or ill fitting dentures; and aphthous ulcers.

Predicate Device:

K042722
Aloclair™ Oral Spray
Sinclair Pharmaceuticals, Ltd
Godalming, Surrey,UK
Product Code-MGQ

K053342

3 Summary of Safety and Effectiveness

Date Summary Prepared:	February 15, 2007
Applicants Name:	Ricerfarma Srl Via Egadi, 7-20144 Milano, Italy
Contact Person:	Paul Ketteridge, (Consultant to Ricerfarma) 303 Patleigh Road Catonsville, MD 21228 443 729-0836 p.kett@comcast.net
Device Name:	Gengigel® Gel.
Classification Name:	Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code:	MGQ
CFR Section:	None
Device Class:	Unclassified
Classification Panel:	General and Plastic Surgery

Indications: Gengigel® Gel provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: oral surgery; traumatic ulcers caused by braces or ill fitting dentures; and aphthous ulcers.

Predicate Devices

K040950
Aloclair™ Oral Gel
Sinclair Pharmaceuticals, Ltd
Godalming, Surrey,UK
Product Code-MGQ

K053342

3 Summary of Safety and Effectiveness

Date Summary Prepared: February 15, 2007

Applicants Name: Ricerfarma Srl
Via Egadi, 7-20144
Milano, Italy

Contact Person: Paul Ketteridge, (Consultant to Ricerfarma)
303 Patleigh Road
Catonsville, MD 21228
443 729-0836
p.kett@comcast.net

Device Name: Gengigel® Mouthrinse.
Classification Name: Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code: MGQ
CFR Section: None
Device Class: Unclassified
Classification Panel: General and Plastic Surgery

Indications: Gengigel® Mouthrinse provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: oral surgery; traumatic ulcers caused by braces or ill fitting dentures; and aphthous ulcers.

Predicate Device

K023155
Aloclair™ Oral Rinse
Sinclair Pharmaceuticals, Ltd
Godalming, Surrey,UK
Product Code-MGQ

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ricerfarma SRL
C/O Mr. Paul Ketteridge
Consultant
PD Regulatory Consulting, LLC
303 Patleigh Road
Catonsville, Maryland 21228

MAR 13 2007

Re: K053342
Trade/Device Name: Gengigel® Mouthrinse
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MGQ
Dated: February 15, 2007
Received: February 16, 2007

Dear Mr. Ketteridge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

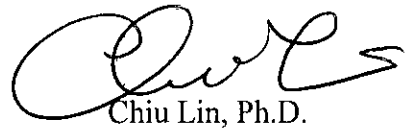
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053342

Gengigel® Junior
Premarket Notification K053342
February 15, 2007

1 Indications for Use

510(k) Number (if known): K053342

Device Name: _Gengigel® Junior

Indications for Use:

Gengigel® Gengigel® Junior provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: oral surgery; traumatic ulcers caused by braces or ill fitting dentures; and aphthous ulcers.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __XXX_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___ *(Posted November 13, 2003)*

Susan Runner

K053342

K053342

Gengigel® Prof Fluid
Premarket Notification K053342
February 15, 2007

1 Indications for Use

510(k) Number (if known): K053342

Device Name: _Gengigel® Prof Fluid

Indications for Use:

Gengigel®	Gengigel® Prof Fluid adheres to the oral mucosa and forms a protective film over the lesions and irritation due to various etiologies, including: oral surgery; traumatic ulcers caused by, braces or ill fitting dentures; diffuse aphthous ulcers; and oral mucositis/stomatitis (which may be caused by chemotherapy or radiotherapy). Gengigel® Prof Fluid relieves pain by providing a barrier to protect the area from ongoing insult and discomfort.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K053342

K053342

1 Indications for Use

510(k) Number (if known): K053342

Device Name: _Gengigel® Spray

Indications for Use:

Gengigel®	Gengigel Spray provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: oral surgery; traumatic ulcers caused by braces or ill fitting dentures; and aphthous ulcers.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___XX____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K053342

K053342

Gengigel® Prof Gel
Premarket Notification K053342
February 15, 2007

1 Indications for Use

510(k) Number (if known): K053342

Device Name: _Gengigel® Prof Gel

Indications for Use:

Gengigel®	Gengigel® Prof Gel adheres to the oral mucosa and forms a protective film over the lesions and irritation due to various etiologies, including: oral surgery; traumatic ulcers caused by, braces or ill fitting dentures; diffuse aphthous ulcers; and oral mucositis/stomatitis (which may be caused by chemotherapy or radiotherapy). Gengigel® Prof Gel relieves pain by providing a barrier to protect the area from ongoing insult and discomfort.

Prescription Use ____xx___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K053342

K053342

Gengigel® Gel
Premarket Notification K053342
February 15, 2007

1 Indications for Use

510(k) Number (if known): K053342

Device Name: _Gengigel® Gel

Indications for Use:

Gengigel®	Gengigel Gel provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: oral surgery; traumatic ulcers caused by braces or ill fitting dentures; and aphthous ulcers.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __XX_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K053342

K053342

1 Indications for Use

510(k) Number (if known): K053342

Device Name: _Gengigel® Mouthrinse

Indications for Use:

Gengigel Mouthrinse provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: oral surgery; traumatic ulcers caused by braces or ill fitting dentures; and aphthous ulcers.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____XX___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K053342